

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

H. LUNDBECK A/S, TAKEDA)	
PHARMACEUTICAL COMPANY LTD.,)	
TAKEDA PHARMACEUTICALS U.S.A.,)	
INC., TAKEDA PHARMACEUTICALS)	
INTERNATIONAL AG, and TAKEDA)	
PHARMACEUTICALS AMERICA, INC.,)	
)	C.A. No. 18-88-LPS
Plaintiffs,)	CONSOLIDATED
)	
v.)	PUBLIC VERSION
)	
APOTEX INC., et al.,)	
)	
Defendants.)	

**LUPIN'S REPLY LETTER BRIEF IN SUPPORT OF EXPEDITED MOTION
TO ENFORCE PRIOR ORDER AND RENEWED MOTION TO STRIKE
PORTIONS OF PLAINTIFFS' EXPERT REPORTS**

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OF COUNSEL:

Deepro R. Mukerjee
Lance Soderstrom
KATTEN MUCHIN ROSENMAN LLP
575 Madison Avenue
New York, NY 10022-2585
(212) 940-8800

Jitendra Malik
Joseph M. Janusz
Alissa M. Pacchioli
KATTEN MUCHIN ROSENMAN LLP
550 South Tryon Street, Suite 2900
Charlotte, NC 28202-4213
(704) 444-2000

DEVLIN LAW FIRM LLC
James M. Lennon (No. 4570)
1526 Gilpin Avenue
Wilmington, DE 19806
(302) 449-9010
jlennon@devlinlawfirm.com

*Attorneys for Defendants Lupin
Limited and Lupin Pharmaceuticals,
Inc.*

Dear Chief Judge Stark:

I. Introduction – The gamesmanship Plaintiffs are perpetuating is clear. Less than two weeks ago, Plaintiffs stated that this Court only struck “the [REDACTED]” and that the Court’s Order permits Plaintiffs to “continue to assert and present evidence of Lupin’s infringement of the full scope of [Claim 1 of the ’684 patent, claims 5 and 7 of the ’355 patent, and claim 1 of the ’630 patent.]” (D.I. 900, Ex. 1) Every one of those claims, of course, covers the [REDACTED].

Injecting the [REDACTED] into the case once more through reply reports is tantamount to an indirect motion for reconsideration. On one hand, if Lupin sits silently, Plaintiffs win that “motion” and the [REDACTED] is back in. On the other, if Lupin approaches the Court, they now have a forum to argue what they failed to argue before—that the belated [REDACTED] theory is now somehow relevant to theories of infringement related to [REDACTED].

This must end. That Lupin has already expended substantial resources fighting this is prejudicial enough. Lupin returns once more to respectfully request that its motion be granted – again. And, that Plaintiffs be foreclosed from asserting a theory never before disclosed to Lupin, and that Lupin be awarded its reasonable fees for its trouble here.

II. Lupin’s First Motion Sought to Strike Any [REDACTED] Opinions – Lupin concluded its letter brief in support of its motion with an unequivocal request for relief: “Lupin therefore requests that any expert opinions relating to, or alleging the presence of, the [REDACTED] in Lupin’s ANDA products be stricken.” (D.I. 748 at 3.) And the Court granted that relief. Plaintiffs’ attempt to argue that Lupin never sought exclusion of [REDACTED] evidence is simply not true. Their piecemeal citation to Lupin’s original cover motion explaining that some offending paragraphs in the expert reports occasionally included discussion of the [REDACTED] (which were not the subject of Lupin’s original motion) is merely an attempt to distract from what Lupin actually sought, and should be ignored.

Lupin’s original briefing was clear, with extensive discussion as to both: 1) the problem with Plaintiffs’ litigation strategy; and 2) the appropriate and requested relief. *See, e.g., id.* at 2 (explaining that the [REDACTED] was one of [REDACTED] different forms Plaintiffs alleged were present in Lupin’s product, and striking the [REDACTED] would not impact Plaintiffs’ disclosed theories on the [REDACTED]); *id.* at 3 (explaining that Plaintiffs’ contentions never articulated “any theory that Lupin’s ANDA products *contain the* [REDACTED],” much less that they ever accused Lupin of infringing any [REDACTED]) (emphasis added); D.I. 764 at 1 (explaining the impropriety of “disclosing a new theory (and asserting new claims) for the first time in opening expert reports”); *id.* (“Lupin’s motion is directed to the [REDACTED] theory, which was improperly articulated for the first time in opening expert reports.”). Plaintiffs understood the relief sought—to suggest otherwise now is disingenuous at worst and misguided at best.

III. This is Not Proper Rebuttal Testimony – Plaintiffs characterize their reply reports as “discussing the results of analytical testing performed on samples of Lupin’s ANDA product.” (D.I. 900, Ex. 1). But what Plaintiffs neglect to mention is that their experts analyzed [REDACTED] for the first time in these reply reports. Their refusal to

address that point is puzzling—they did actually test [REDACTED] before serving opening reports.¹ If Plaintiffs believed the [REDACTED] was properly part of the case before opening expert reports (which they did), their experts should have included analysis of a [REDACTED]. But they chose not to, and including it now under the guise of a “rebuttal” position is merely an attempted proverbial second bite at the apple. It should be rejected.

But there is more. As noted in prior briefing, Lupin was forced to respond to Plaintiffs opening reports that improperly included the [REDACTED] opinions. Had Plaintiffs only alleged the presence of the [REDACTED] in their opening report, Lupin’s rebuttal report (expectedly) would have been different. Arguing that the [REDACTED] opinions on reply are appropriate because they rebut Dr. Cockcroft’s opinions, which in part rebut the improper opening [REDACTED] opinions, is both circular and nonsensical.

The same is true on the merits. Plaintiffs asserted that Lupin’s ANDA product allegedly comprises the [REDACTED]. But, according to Plaintiffs, they now need to include evidence related to the [REDACTED] to rebut Lupin’s expert’s opinion that Dr. Morin’s testing does not show the presence of [REDACTED]. Why can’t they simply rebut that with the alleged presence of the [REDACTED]s? Lupin disagrees that these forms are present, but that certainly does not justify reviving already stricken evidence through supposed “rebuttal” testimony.

IV. These are Not Proper Items of Proof for Previously Disclosed Infringement Theories – Plaintiffs argument that the [REDACTED] is relevant to their other disclosed infringement theories is similarly flawed. If the presence of the [REDACTED] in Lupin’s ANDA product is relevant to their claims with respect to the [REDACTED], why was that never argued in the briefing on Lupin’s first motion? Did Plaintiffs not believe it was valid then, but believe it is now? The proof is in the pudding—Plaintiffs are seeking a second chance without justification to raise now an argument that could and should have been raised in response to Lupin’s first motion.

This leads to another point that went unanswered by Plaintiffs—based on this argument, do Plaintiffs believe that all of the [REDACTED] opinions in their opening reports are still in the case, despite this Court’s prior Order? It is clear Plaintiffs believe this Court’s prior Order permits them to “assert and present evidence of Lupin’s infringement of the full scope of these claims.” (D.I. 900, Ex. 1) And despite the new contention that Plaintiffs do not intend to allege infringement based on the [REDACTED], the record proves otherwise. *See, e.g.*, D.I. 899, Ex. E, at p. 12 and ¶ 41 (Myerson opining that “Lupin’s ANDA product is characterized by [REDACTED],” using language from the asserted claims); ¶ 45 (stating that certain peaks in a Lupin sample “are much more likely to be characteristic of the [REDACTED].”); ¶ 96 (concluding infringement, referencing opening report opinions, and opining that Lupin’s product contains “the forms of vortioxetine hydrobromide recited in [the asserted claims]”). In fact, Dr. Myerson never once specifies that his infringement opinions relate only to the [REDACTED]—to the contrary, his reply has more mentions of [REDACTED] than those of [REDACTED]. And, Dr. Morin’s reply addresses *only* the [REDACTED]. *Id.*, Ex. D. For these reasons, Lupin respectfully requests that its motion be granted.

¹ These [REDACTED].

Respectfully submitted,

/s/ James M. Lennon

James M. Lennon (No. 4570)

cc: Clerk of Court (via CM/ECF)
All Counsel of Record (via e-mail)